

# **Christina Pramudji**

## **Reliance List *in Addition to Materials Referenced in Report***

### **MDL Wave 1**

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[ETH.MESH.08565137-08565141]
[ETH.MESH.08791917]
[ETH.MESH.08961175-08961176]
[ETH.MESH.10378001-8002]
[ETH.MESH.13698840-59]
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ETH MESH 00082651- 654
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ETH MESH 09268043-045
ETH.MESH.00000172 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call
ETH.MESH.00000173 8/25/11 Registration list for 8/25/11 call
ETH.MESH.00003895 to ETH.MESH.00003895 Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee
ETH.MESH.00019117 to ETH.MESH.00019121 Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.
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ETH.MESH.00127103 to ETH.MESH.00127103 Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley Fronio and Kevin Mahar.
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ETH.MESH.00131149 to ETH.MESH.00131151 Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosima Global Launch Team.
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ETH.MESH.00516424- 427
ETH.MESH.00541708 to ETH.MESH.00541709 Document entitled "Notes from Competitive Ad Board."
ETH.MESH.00541873 to ETH.MESH.00541873 Chart listing Proposed Lab Scheduling for August 4th.



## Production Materials

ETH.MESH.00541876 to ETH.MESH.00541878 Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.
ETH.MESH.00542347 to ETH.MESH.00542348 Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.
ETH.MESH.00542463 to ETH.MESH.00542463 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: 2-Year Clinical Data
ETH.MESH.00547021 to ETH.MESH.00547021 Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.00547036 to ETH.MESH.00547037 Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.
ETH.MESH.00573815 to ETH.MESH.00573815 Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima* Pelvic Floor Repair System) June 2010.
ETH.MESH.00573860 to ETH.MESH.00573878 (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolapse with Tension-free Mesh and Vaginal Support Device."
ETH.MESH.00575580 to ETH.MESH.00575581 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.
ETH.MESH.00575634 to ETH.MESH.00575635 ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."
ETH.MESH.00578081 to ETH.MESH.00578083 Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.
ETH.MESH.00578550 to ETH.MESH.00578550 (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."
ETH.MESH.00579296 to ETH.MESH.00579296 Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolapse Patients.
ETH.MESH.00580588 to ETH.MESH.00580589 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch
ETH.MESH.00592224 to ETH.MESH.00592229 E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima
ETH.MESH.00594528 Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.
ETH.MESH.00595468 to ETH.MESH.00595470 Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.
ETH.MESH.00595889 to ETH.MESH.00595890 Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.
ETH.MESH.00604183 to ETH.MESH.00604186 Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.
ETH.MESH.00631782 to ETH.MESH.00631784 FDA Letter re: K063562 Gynecare Prosima
ETH.MESH.00679637 to ETH.MESH.00679640 Email string, top one from Zenobia Walji to Ron Naughton, et al. re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.
ETH.MESH.00759327 to ETH.MESH.00759335 Document entitled "Experience what's new in incontinence and pelvic floor repair." 2010 ICS IUGA Executive Agenda
ETH.MESH.00800521 to ETH.MESH.00800522 Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.

## Production Materials

ETH.MESH.00806974 to ETH.MESH.00806975 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.00807570 to ETH.MESH.00807570 Revised Chart listing Proposed Lab Schedule
ETH.MESH.00807772 to ETH.MESH.00807774 Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.
ETH.MESH.00807972 to ETH.MESH.00807973 Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.00808121 to ETH.MESH.00808122 Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.
ETH.MESH.00817181 to ETH.MESH.00817181 Email from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.
ETH.MESH.00820634 to ETH.MESH.00820634 Invitation to participate in Gynecare Prosima Virtual Round Table
ETH.MESH.00832749 to ETH.MESH.00832754 Risk Management Report: Prosima Pelvic Floor Repair Kit
ETH.MESH.00833948 to ETH.MESH.00833949 Email from David Robinson to Jessica Shen re: Prosima Study.
ETH.MESH.00834910 to ETH.MESH.00834911 Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.
ETH.MESH.00840886 to ETH.MESH.00840887 Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.
ETH.MESH.00843043 Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.
ETH.MESH.00849014-ETH.MESH.00849017
ETH.MESH.00850335 to ETH.MESH.00850336 Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.
ETH.MESH.00851319 to ETH.MESH.00851321 E-mail string, top one from Piet Hinoul to Clifford Volpe and David Robinson re dimensions of the PROSIMA implant
ETH.MESH.00851319-ETH.MESH.00851321
ETH.MESH.00895089 to ETH.MESH.00895091 Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.
ETH.MESH.00921692 to ETH.MESH.00921694 Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.
ETH.MESH.00925065 to ETH.MESH.00925067 Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.
ETH.MESH.01136239 to ETH.MESH.01136240 Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.
ETH.MESH.01198058 to ETH.MESH.01198058 (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."
ETH.MESH.01200286 to ETH.MESH.01200286 Powerpoint: Gynecare Prosima : Overview.
ETH.MESH.01201973 to ETH.MESH.01201973 Propsed Lab Schedule (2nd Revision)
ETH.MESH.01237077 to ETH.MESH.1237079 Email from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier.
ETH.MESH.01244824 to ETH.MESH.01244826 Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.
ETH.MESH.01411037 to ETH.MESH.01411039 Summary re: Project Mint

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ETH.MESH.0141137 to ETH.MESH.0141039 Document re: summary of changes in mesh implant from Project Mint to final production.
ETH.MESH.01593930 to ETH.MESH.01593942 Prosima Clinical Expert Report (not signed or dated).
ETH.MESH.01638150 to ETH.MESH.01638150 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System Background; Halina Zyczynski, M.D.
ETH.MESH.01678340 to ETH.MESH.01678340 Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.
ETH.MESH.01707963 to ETH.MESH.01707963 Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.01708116 to ETH.MESH.01708117 Email string, top one from Bart Pattyson to Georgia Long re: TVT Abbrevio and Prosima training; cc: Elizabeth Kolb, Andrew Meek.
ETH.MESH.01708180 to ETH.MESH.01708180 Chart listing financial information re: preceptors.
ETH.MESH.01708190 to ETH.MESH.01708190 Chart listing financial information re: preceptors.
ETH.MESH.01730626 to ETH.MESH.01730629 Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.
ETH.MESH.01803816 to ETH.MESH.01803818 Summary re: Project Mint
ETH.MESH.01821586 to ETH.MESH.01821587 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Bob Roda, et al.
ETH.MESH.01821586 to ETH.MESH.01821587 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Dan Smith, et al.
ETH.MESH.01821586-587
ETH.MESH.02010349 to ETH.MESH.02010362 Prosima Clinical Expert Report signed by David Robinson
ETH.MESH.02066770-771
ETH.MESH.02114615 to ETH.MESH.02114616 Email string, top one from Libby Lewis to Donna Abely, et al. re: Remaining 2010 labs.
ETH.MESH.02156379-380
ETH.MESH.02217343-44
ETH.MESH.02229051 - cover sheet Biomechanics
ETH.MESH.02229051 Biomechanics video
ETH.MESH.02229051 to ETH.MESH.02229051 Video: "Biomechanics"
ETH.MESH.02229054 - cover sheet What to expect
ETH.MESH.02229054 to ETH.MESH.02229054 Video: "What to Expect"
ETH.MESH.02229054 What to expect video
ETH.MESH.02229055 - cover sheet VSD case series
ETH.MESH.02229055 to ETH.MESH.02229055 Video: "VSD Case Series 1"
ETH.MESH.02229055 VSD Case series 1 - PROS-276-11_PROSIMA_CASE_SERIES_V12_CA
ETH.MESH.02232685 Marketing 1
ETH.MESH.02232685 to ETH.MESH.02232685 Marketing: "Your Proof: Her dance class."
ETH.MESH.02233410 2009 US Sales Meeting Brief
ETH.MESH.02233410 to ETH.MESH.02233406 US Launch - Premarket Preparation (PMP)
ETH.MESH.02233417 Prosima New Product Request Form
ETH.MESH.02233417 to ETH.MESH.02233417 Prosima New Product Request Form
ETH.MESH.02233418 Surgical Technique
ETH.MESH.02233418 to ETH.MESH.02233438 Prosima - Surgical Technique

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ETH.MESH.02233439 to ETH.MESH.02233451 A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.
ETH.MESH.02233439 US Training 1-year clinical data
ETH.MESH.02233452 to ETH.MESH.02233467 Prosima - Background and Development History
ETH.MESH.02233452 US Training - Background & history
ETH.MESH.02233539 New Product Request Form 2
ETH.MESH.02233539 to ETH.MESH.02233539 Prosima - New Product Request Form
ETH.MESH.02233540 2009 Sales training
ETH.MESH.02233540 to ETH.MESH.02233625 Prosima - 2009 Sales Training Program
ETH.MESH.02233605 B&W Webinar invite
ETH.MESH.02233605 to ETH.MESH.02233605 (B&W) Webinar Invite "The treatment of Symptomatic Moderate Pelvic Organ Prolapse."
ETH.MESH.02233640 B&W 2-year clinical data
ETH.MESH.02233640 to ETH.MESH.02233640 (B&W) Prosima - Module 4: 2-Year Clinical Data
ETH.MESH.02233651 to ETH.MESH.02233673 One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device. Results from the International Multicenter Gynecare Prosima™ Study.
ETH.MESH.02233674 KF Marketing 1
ETH.MESH.02233674 to ETH.MESH.02233692 (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"
ETH.MESH.02233699 Dr. Carey white paper
ETH.MESH.02233699 to ETH.MESH.02233710 Prosima - An Interview with Dr. Marcus P. Carey.
ETH.MESH.02233713 Objective success learning guide
ETH.MESH.02233713 to ETH.MESH.02233714 Objective Success Rate Learning Guide
ETH.MESH.02233726 Ethicon360 12.09
ETH.MESH.02233726 to ETH.MESH.02233727 Prosima Product Page on Ethicon-360
ETH.MESH.02233728 to ETH.MESH.02233728 (native) Gynecare Prosima™ Key Procedural Steps
ETH.MESH.02233834 B&W 2009 Sales Aid Guide
ETH.MESH.02233834 to ETH.MESH.02233834 (B&W) 2009 Sales Aid Guide
ETH.MESH.02233840 MRI Flashcard
ETH.MESH.02233840 to ETH.MESH.02233841 MRI Flashcard "Prosimia - The first fixationless mesh system that maintains anatomical position."
ETH.MESH.02233842 to ETH.MESH.02233842 Virtual Round Table Registration Form
ETH.MESH.02233842 VRT rsvp 9.2010
ETH.MESH.02233843 to ETH.MESH.02233849 Clinical Study Findings Discussion for Gynecare Prosima™ by Piet Hinoul (Audio Transcript).
ETH.MESH.02233851 to ETH.MESH.02233851 Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."
ETH.MESH.02233857 AJOG Press Release
ETH.MESH.02233857 to ETH.MESH.02233859 AJOG Press Release (Draft)
ETH.MESH.02233862 AALG in booth presentation
ETH.MESH.02233862 to ETH.MESH.02233880 AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.
ETH.MESH.02233881 to ETH.MESH.02233888 Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.

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ETH.MESH.02233961 to ETH.MESH.02233961 Virtual Round Table Follow-up Letter.
ETH.MESH.02233961 VRT follow-up
ETH.MESH.02233962 to ETH.MESH.02233962 Virtual Round Table Follow-up Letter.
ETH.MESH.02233962 VRT2 follow-up
ETH.MESH.02233963 to ETH.MESH.02233963 Virtual Round Table Invitation
ETH.MESH.02233963 VRT invite 9.2010
ETH.MESH.02233964 B&W Prosima DVD
ETH.MESH.02233964 to ETH.MESH.02233964 (B&W) Prosima DVD
ETH.MESH.02234001 KF Marketing 1a
ETH.MESH.02234001 to ETH.MESH.02234002 (Marketing) The Gynecare Prosima™ Pelvic Floor Repair System Story
ETH.MESH.02234005 Sales Training 20
ETH.MESH.02234005 to ETH.MESH.02234171 Prosima Sales Training Program
ETH.MESH.02234173 to ETH.MESH.02234177 Prosima Messgaging practice Coaching Check List
ETH.MESH.02234173 Training checklist
ETH.MESH.02237107 Pt Ethicon epiphany
ETH.MESH.02237107 to ETH.MESH.02237115 Introducing Gynecare Prosima for Ethicon Epiphany 247.
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both
Eth.Mesh.02293981 Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Response
ETH.MESH.02318553 to ETH.MESH.02318554 Gynecare Prosima™ Combined Pelvic Floor Repair System Clinical Strategy.
ETH.MESH.02322037 to ETH.MESH.02322039 Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial.
ETH.MESH.02322037-039
ETH.MESH.02341398 to ETH.MESH.02341453 Prosima IFU
ETH.MESH.02597949 to ETH.MESH.02597950 Hinoul, P., et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine."
ETH.MESH.02599918 to ETH.MESH.02599920 Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosima Data Conference Call.
ETH.MESH.02967410 to ETH.MESH.02967412 Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.
ETH.MESH.03048942 to ETH.MESH.03048942 Document entitled "New" Mint January 05, 2006.
ETH.MESH.03049774 to ETH.MESH.03049775 Gynecare Prosima* Combined Pelvic Floor Repair System: Clinical Strategy.
ETH.MESH.03056578 to ETH.MESH.03056580 Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima* investigator bulletin.
ETH.MESH.03109341 to ETH.MESH.03109341 Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.
ETH.MESH.03160821 to ETH.MESH.03160821 Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.
ETH.MESH.03160822 to ETH.MESH.03160823 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.03160827 to ETH.MESH.03160828 Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.
ETH.MESH.03162936 to ETH.MESH.03162938 Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.



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ETH.MESH.03393725 to ETH.MESH.03339731 Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract
ETH.MESH.03396246 to ETH.MESH.03396246 VSD Patient Information (Slim Jim) - "Stop Coping Start Living."
ETH.MESH.03427757 to ETH.MESH.03427759 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.
ETH.MESH.03439842 to ETH.MESH.03439846 Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"
ETH.MESH.03440816 to ETH.MESH.03440836 Prosima Revised Webinar Deck - Overview
ETH.MESH.03471308 to ETH.MESH.03471308 Chart entitled "Pedm Monthly Status."
ETH.MESH.03612364 to ETH.MESH.03612364 Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.
ETH.MESH.03626267 to ETH.MESH.03626269 Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.03643392 to ETH.MESH.03643395 Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQs and Customer Letter.
ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results
Eth.Mesh.03962244 Dear Surgeon letter 7/18/11
ETH.MESH.03984409 to ETH.MESH.03984410 Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.
ETH.MESH.03989722 to ETH.MESH.03989723 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.
ETH.MESH.03989781 to ETH.MESH.03989782 Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.
ETH.MESH.03991591 to ETH.MESH.03991592 Memo re: Gynecare Studies; created by Randall Gore.
ETH.MESH.04042511 to ETH.MESH.04042512 Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."
ETH.MESH.04077172 to ETH.MESH.04077172 Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010
ETH.MESH.04206959
ETH.MESH.04381806 to ETH.MESH.04381819 Literature Review on Biocompatibility of Prolene Sutures and Implants
ETH.MESH.04427456 to ETH.MESH.14427457 FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems
Eth.Mesh.04543335 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
Eth.Mesh.04543336 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04543336- POP Surgical Mesh Discussion 09.12
ETH.MESH.04550996 to ETH.MESH.04550997 Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.
ETH.MESH.04550996 to ETH.MESH.04550997 Email string, top one from Piet Hinoul to Marcus Carey re: Prosima VSD.
ETH.MESH.04551757 to ETH.MESH.04551795 E-mail with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM
Eth.Mesh.04551946 Ethicon Gynecare WW Commercialization Decision – US Surgeon Letter 6/1/12



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Eth.Mesh.04554662 Ethicon Gynecare WW Commercialization Decision – US Frequently Asked Questions 6/1/12
Eth.Mesh.04567174 Ethicon Gynecare US Commercialization Decision – US Discussion Guide for Use with Customers 5/15/12
Eth.Mesh.04567674 Ethicon Gynecare US Commercialization Decision – Core Messages 5/15/12
Eth.Mesh.04567677-04567679 Frequently asked questions 5/15/12
Eth.Mesh.04567680-04567681 Message from Laura Angelini to Internal WW Associates 5/15/12
Eth.Mesh.04567686-04567679 US Sales Call Script for Matt Henderson 5/15/12
Eth.Mesh.04567695 Ethicon Gynecare WW Commercialization Decision – Core Messages 6/1/12
Eth.Mesh.04567698 Ethicon Gynecare WW Commercialization Decision – Standby Statement 6/1/12
Eth.Mesh.04567707 Ethicon Gynecare WW Commercialization Decision – Chuck Austin Message to WW General Surgery Employees 6/1/12
Eth.Mesh.04567726 Ethicon Gynecare WW Commercialization Decision – Tim Schmid message to US General Surgery Employees 6/1/12
ETH.MESH.04568519 to ETH.MESH.04568519 Email from Matt Henderson to Tim Schmid re: 522 Communication Recap.
ETH.MESH.05092843 to ETH.MESH.05092843 Chart listing lab schedule for August 11th.
ETH.MESH.05106233 to ETH.MESH.05106234 Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder: Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.
ETH.MESH.05164225 to ETH.MESH.05164226 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesg and a vaginal support device."
ETH.MESH.05165675 to ETH.MESH.05165677 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.
ETH.MESH.05217098 to ETH.MESH.05217100 FDA Clearance Letter, Modified PROLENE
ETH.MESH.05217103 to ETH.MESH.05217144 Letter to FDA re: Notification of Intent
ETH.MESH.05343480 to ETH.MESH.05343482 Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.
ETH.MESH.05343757 to ETH.MESH.05343758 Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.
ETH.MESH.05469908 to ETH.MESH.05469912 Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.
ETH.MESH.05469908-912
ETH.MESH.05571741 to ETH.MESH.05571741 Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.
ETH.MESH.05573916 to ETH.MESH.05573917 Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.
ETH.MESH.05741094 to ETH.MESH.05741094 Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.
ETH.MESH.05741890 to ETH.MESH.05741891 Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.
ETH.MESH.05835298 to ETH.MESH.05835308 Pelvic Organ Prolapse - Patient Counseling Guide.
ETH.MESH.05837063 to ETH.MESH.05837110 Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.

Production Materials

ETH.MESH.05840629 to ETH.MESH.05840629 Powerpoint Presentation entitled "Continuum of Education."
ETH.MESH.05922038 to ETH.MESH.05922038 Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.
ETH.MESH.05947160 to ETH.MESH.05947163 Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up_Gynecare_Reminder; cc: Fernando Nassif, et al.
ETH.MESH.05967586 to ETH.MESH.05967587 Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.
ETH.MESH.06113091 to ETH.MESH.06113092 Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.
ETH.MESH.06124656 to ETH.MESH.06124657 Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.
ETH.MESH.06124954 to ETH.MESH.06124955 Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.
ETH.MESH.06125000 to ETH.MESH.06125001 Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.
ETH.MESH.06125058 to ETH.MESH.06125058 Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.
ETH.MESH.06125098 to ETH.MESH.06125098 Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.
ETH.MESH.06125277 to ETH.MESH.06125277 Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.
ETH.MESH.06125309 to ETH.MESH.06125309 Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.
ETH.MESH.06125502 to ETH.MESH.06125502 Email string, top one from Georgia Long to Bart Pattyson re: may 8th.
ETH.MESH.06151466 to ETH.MESH.06151467 Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.
ETH.MESH.06238611 to ETH.MESH.06238611 Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.
ETH.MESH.06255523 to ETH.MESH.06255534 Gynecare Prosima™ Pelvic Floor Repair System. "An Expert Interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the Inventor of the Gynecare Prosima System."
ETH.MESH.06388151 to ETH.MESH.06388151 Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints
ETH.MESH.06480608 to ETH.MESH.06480609 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.06482821 to ETH.MESH.06482822 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.
ETH.MESH.06585815 to ETH.MESH.06585815 Powerpoint: Agenda
ETH.MESH.06591558 to ETH.MESH.06591559 Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.
ETH.MESH.06769156 to ETH.MESH.06769156 Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.
ETH.MESH.07105727 to ETH.MESH.07105727 Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.

## Production Materials

ETH.MESH.07189091 to ETH.MESH.07189091 Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.
ETH.MESH.07190144 to ETH.MESH.07090145 Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.
ETH.MESH.07219196 to ETH.MESH.07219209 Clinical Expert Report - Prosima <sup>™</sup> signed by David Robinson.
ETH.MESH.07229215 to ETH.MESH.07229245 Clinical Expert Report - Prosima <sup>™</sup> signed by Piet Hinoul.
ETH.MESH.07296496 to ETH.MESH.07296496 Chart listing Week Schedule and Lab Flow.
ETH.MESH.07308636 to ETH.MESH.07308637 Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.
ETH.MESH.07324554-555
ETH.MESH.07374762 to ETH.MESH.07374763 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.07379573 to ETH.MESH.07379574 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.
ETH.MESH.07384790 to ETH.MESH.07384791 Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.
Eth.Mesh.07462313 Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response
ETH.MESH.07587090 to ETH.MESH.07587091 Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.
ETH.MESH.07628243 to ETH.MESH.07628243 EWH&U Gynecare Prosima <sup>™</sup> Pelvic Floor Repair System Faculty Checklist.
ETH.MESH.07630654 to ETH.MESH.07630654 Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.
ETH.MESH.07631488 to ETH.MESH.07631488 Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.
ETH.MESH.07631752 to ETH.MESH.07631753 Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.
ETH.MESH.07631967 to ETH.MESH.07631968 Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.
ETH.MESH.07632042 to ETH.MESH.07632042 Event request form for Sepulveda Preceptorship.
ETH.MESH.07632042 to ETH.MESH.07632043 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.07636090 to ETH.MESH.07636090 Prosima Cadaver Lab Invitation
ETH.MESH.07653362 to ETH.MESH.07653363 Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.07931680 to ETH.MESH.07931681 Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.07951163 to ETH.MESH.07951163 Document re: Prosima's apical/anatomical success rates and functional outcomes.
ETH.MESH.07953429 to ETH.MESH.07953433 EWH&U 2011 Field Visit Letter
ETH.MESH.07977911 to ETH.MESH.07977911

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ETH.MESH.08021804 to ETH.MESH.08021807 Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.
ETH.MESH.08023741 to ETH.MESH.08023744 Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.
ETH.MESH.08033153 to ETH.MESH.08033153 Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Luber, Charles W. Nager, Emily S. Lukacz.
ETH.MESH.08048738 to ETH.MESH.08048740 Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.
ETH.MESH.08066452 to ETH.MESH.08066452
ETH.MESH.08135444 to ETH.MESH.08135444 Gynecare Prosima - Pelvic Floor Repair System Proctorship
ETH.MESH.08139049 to ETH.MESH.08139118 Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.
ETH.MESH.08161765 to ETH.MESH.08161765 Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.
ETH.MESH.08169582 to ETH.MESH.08169620 Surgical Practice of POP survey on Survey Monkey.
ETH.MESH.08290691 to ETH.MESH.08290691
ETH.MESH.08309057 to ETH.MESH.08309092 Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."
ETH.MESH.08375158 to ETH.MESH.08375159 Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TVT Abbrevio, Prosima, TVT Exact.
ETH.MESH.08384247 to ETH.MESH.08384247
ETH.MESH.08384270 to ETH.MESH.08384270 Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garris.
Eth.Mesh.08421628 Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12
ETH.MESH.08492824
ETH.MESH.08492824 to ETH.MESH.08492824 Strategic Business Team Meeting - Meeting Notes
Eth.Mesh.08640676 Jones email 4/04/08 re Prosima update for RBDs
ETH.MESH.08945734 to ETH.MESH.08945735 ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."
ETH.MESH.08945742 to ETH.MESH.08945744 Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.
ETH.MESH.08945836 to ETH.MESH.08945840 Document entitled "Gynecare Prosima Claims List."
ETH.MESH.08948364 to ETH.MESH.08948365 Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.
ETH.MESH.08951725 to ETH.MESH.08951726 Email string, top one from Tom Affeld to Kevin Frost re: Prosima 2 year summary for eClinical Compendium.
ETH.MESH.08962682 to ETH.MESH.08962683 Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.
ETH.MESH.08962684 to ETH.MESH.08962685 Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.
ETH.MESH.08971152 to ETH.MESH.08971153 Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.

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ETH.MESH.08971269 to ETH.MESH.08971270 Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.
ETH.MESH.08971271 to ETH.MESH.08971272 Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.
ETH.MESH.08971309 to ETH.MESH.08971314 Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.
ETH.MESH.08988155 to ETH.MESH.08988155 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.
ETH.MESH.08988298 to ETH.MESH.08988417 EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.
ETH.MESH.09050450 to ETH.MESH.09050450 Memorandum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).
ETH.MESH.09128451 to ETH.MESH.09128451 Chart entitled "Faculty Training."
Eth.Mesh.09128545 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11
ETH.MESH.09128545- POP Surgical Mesh Discussion 08.25
ETH.MESH.09138054 to ETH.MESH.09138055 Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinis, M.D.
ETH.MESH.09142383 to ETH.MESH.09142384 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.09142511 to ETH.MESH.09142511 (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.
ETH.MESH.09144349 to ETH.MESH.09144349 Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.
ETH.MESH.09191424 to ETH.MESH.09191426 Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.
ETH.MESH.09207059 to ETH.MESH.09207059 Chart entitled "Grier."
ETH.MESH.09218452 to ETH.MESH.09218453 Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.
ETH.MESH.09283030 to ETH.MESH.09283030 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283031 to ETH.MESH.09283031 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283032 to ETH.MESH.09283032 Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283033 to ETH.MESH.09283033 Spreadsheet re: Budget Summary
ETH.MESH.09283034 to ETH.MESH.09283034 Spreadsheet re: Integrated Marketing
ETH.MESH.09283035 to ETH.MESH.09283035 Spreadsheet re: Summary
ETH.MESH.09283036 to ETH.MESH.09283036 Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283037 to ETH.MESH.09283037 Spreadsheet re: Budget Summary
ETH.MESH.09283038 to ETH.MESH.09283038 Spreadsheet re: Integrated Marketing
ETH.MESH.09290755 to ETH.MESH.09290755 Spreadsheet re: Q1 2012 Open PO Summary
ETH.MESH.09290760 to ETH.MESH.09290760 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09290767 to ETH.MESH.09290767 Spreadsheet re: Uterine Health
ETH.MESH.09290769 to ETH.MESH.09290769 Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary
ETH.MESH.09290772 to ETH.MESH.09290772 Spreadsheet re: Budget Summary
ETH.MESH.09300480 to ETH.MESH.09300480 Spreadsheet re: Prosima All Day
ETH.MESH.09625725 to ETH.MESH.09625729 Government Submissions Log Sheet



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ETH.MESH.09625731 to ETH.MESH.09625737 FDA Letter. re: approved drug application for polypropylene suture.
ETH.MESH.09625816 to ETH.MESH.09625816 FDA letter re: receipt of drug application for polypropylene suture.
ETH.MESH.09625817 to ETH.MESH.09625817 Letter to FDA re: new drug application for Polypropylene Suture.
ETH.MESH.09629447 to ETH.MESH.09629448 FDA Labeling Approval for Prolene
ETH.MESH.09630649 to ETH.MESH.09630649 FDA Letter re: package insert for Prolene.
ETH.MESH.09634081 to ETH.MESH.09634081 Sections 6 re: adverse effects.
ETH.MESH.09634299 to ETH.MESH.09634303 FDA Letter re: approval of PMA supplement.
ETH.MESH.09634318 to ETH.MESH.09634318 Prolene Package Insert.
ETH.MESH.09634662 to ETH.MESH.09634663 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09634664 to ETH.MESH.09634688 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.10048035 to ETH.MESH.10048036 Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.
ETH.MESH.10179518 to ETH.MESH.10179636 Clinical Evaluation Report - Gynecare Gynemesh™ PS Nonabsorbable Prolene™ Soft Mesh signed by Piet Hinoul.
ETH.MESH.10224077 to ETH.MESH.10224077 Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.
ETH.MESH.10232708 to ETH.MESH.10232708 Email from Stevan Barendse to Greg Prine re: Prosima targets.
ETH.MESH.10376963
ETH.MESH.10384309-310
ETH.MESH.10399553 to ETH.MESH.10399554 Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.
ETH.MESH.10608341 to ETH.MESH.10608357 Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.
Eth.Mesh.10817931 Pelvic Mesh Post-Market Surveillance Orders April 2012
ETH.MESH.10960414 to ETH.MESH.10960414 Email from Christopher O'Hara to Francois Barbe, et al. re: VRT for Prosima.
ETH.MESH.11048537 to ETH.MESH.11048538 Prosima E-blast No. 1 "The Proof of Success."
ETH.MESH.11448841 Conference Participant Report 8/25/11
ETH.MESH.11518663 to ETH.MESH.11518665 Email string, top one from Melissa Doyle to Arthur Mourtzinis re: Agenda for tomorrow's lab.
ETH.MESH.11522550 to ETH.MESH.11522551 Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.
ETH.MESH.11523079 to ETH.MESH.11523079 Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.
ETH.MESH.11524125 to ETH.MESH.11524128 Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.
ETH.MESH.11536046 to ETH.MESH.11536046 Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.
ETH.MESH.11905619 to ETH.MESH.11905619 Spreadsheet: Prosima Virtual Roundtable Calls &Targets



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ETH.MESH.12897617 to ETH.MESH.12897678 Clinical Evaluation Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.13314554 to ETH.MESH.13314554 Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.
Eth.Mesh.13532200 Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12
ETH.MESH.13592561 to ETH.MESH.13592561 Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"
ETH.MESH.13618003 to ETH.MESH.13618004 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.13618029 to ETH.MESH.13618031 EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."
ETH.MESH.13622000 to ETH.MESH.13622070 Prosima Trainee Deck Distribution
ETH.MESH.1363575.NATIVE
ETH.MESH.13645631 to ETH.MESH.13645631 DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.
ETH.MESH.13698543 to ETH.MESH.13698543 Prosima Marketing Material Roll-Out Letter.
ETH.MESH.13699674 to ETH.MESH.13699754 Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.
ETH.MESH.13756212 to ETH.MESH.13756218 Clinical study Finding Discussion for Gynecare Prosima™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).
ETH.MESH.13756219 to ETH.MESH.13756219 Gynecare Prosima™ Pelvic Floor Repair System MRI Address
ETH.MESH.13756384 to ETH.MESH.13756384 Prosima Virtual Round Table Trainee Confirmation
ETH.MESH.13756409 to ETH.MESH.13756409 Prosima Virtual Round Table Preceptor Follow-up and Invitation.
ETH.MESH.13756416 to ETH.MESH.13756417 Prosima Virtual Round Table Preceptor Confirmation.
ETH.MESH.13869166 to ETH.MESH.13869166 Powerpoint: Mint Project - Pelvic Floor Repair.
ETH.MESH.14427453 to ETH.MESH.14427455 FDA Clearance Letter re: K063562 Gynecare Prosima™
ETH.MESH.14427459 to ETH.MESH.14427543 Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.
ETH.MESH.14427562 to ETH.MESH.14427563 Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.14427564 to ETH.MESH.14427565 FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)
ETH.MESH.14427567 to ETH.MESH.14427569 Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.
ETH.MESH.14427578 to ETH.MESH.14427761 TraditionsI 510(k) Premarket Notification Gynecare Prosima™ Pelvic Floor Repair System.
ETH.MESH.15958178 to ETH.MESH.15958182 Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQs and Customer Letter.
Eth.Mesh.16259973 Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports
ETH.MESH.16350627 to ETH.MESH.16350628 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.

Production Materials

ETH.MESH.16352932 to ETH.MESH.16352934 Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.
ETH.MESH.16352932-934
ETH.MESH.17669942 to ETH.MESH.17669942 Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.17748760 to ETH.MESH.17748761 E-mail from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.17748760-761- Email 4.25.11 FW: 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.18844812 to ETH.MESH.18844812 Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse.
ETH.MESH.19308264 to ETH.MESH.19308265 Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.
ETH.MESH.19310234 to ETH.MESH.19310238 Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TVT-O
ETH-00797 to ETH-00829 510(k) Notification Gynemesh Prolene™ Soft Nonabsorbable Synthetic Surgical Mesh.
ETH-00807 to ETH-00808 FDA Clearance letter for Gynemesh soft mesh for pelvic floor repair
ETH-00830 to ETH-00861 Labeling/Package Insert
ETH-00862 to ETH-00893 Test Method for the Determination of Mesh Burst Strength for Prolene Soft Mesh.
ETH-00894 to ETH-00927 Medical Literature
ETH-01816 to ETH-01817 FDA Clearance Letter, Prolene Soft Mesh (K001122)
Ethicon Biocompatibility Risk Assessment for Gynecare Prolift Total Pelvic Floor Repair System dated 1.19.05 [ETH.MESH.01310817 – 10829]
Ethicon Final Report, PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035)
Ethicon informs FDA of discontinuation [ETH.MESH.04005090]
Ethicon informs FDA of discontinuation [ETH.MESH.04005090-91]
Ethicon Technical Report: Assessment of Competitor Pelvic Floor Repair Meshes, Version 1; Study Number: CPC-2006-0552; JJ-HMREV-00016715
Ethicon Women's Health & Urology — Clinical Compendium — Sales Rep Positioning [ETH.MESH.0011879; ETH.MESH.00093830]
Ethicon's Cover Letter Response to TVT Secur 522 Order [ETH.MESH.04474731]
Ethicon's Notification to FDA regarding Decommercialization [ETH.MESH.04005095-96]
Ethicon's Notification to FDA to Decommercialize [ETH.MESH.04005092-93]
Ethicon's TVT Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TVT Securm System [ETH.MESH.04474733]
EWHU Faculty and PF User Conference Calls Outline
Exh. 10 Gynecare Prolift IFU dated 2004 [ETH-00295 – 00300]
Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512 [ETH-01363 – 01365]
Exh. 59 – Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile (2 pages)
FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29) [ETH.MESH.04554687]
FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11 [ETH.MESH.06049894-96]

## Production Materials

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence issued 10.20.08; Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08 [ETH.MESH.02105765-02105771]
FDA's Response to proposed study plan-04.02.2012 [ETH.MESH.04567040-44]
FDA's Resposne to Discontinuation and Agreement to Hold 522 Responses [ETH.MESH.04567080]
FDA's Resposne to Discontinuation Notification-07.09.2012 [ETH.MESH.04927339-40]
Final Report, PSE Accession No. 97-0197, Project No. 16672 [ETH.MESH.5315252-65]
Guidance for Industry and FDA Staff. "Class II Special Controls Guidnace Document: Surgical sutures; Guidnace for Industry and FDA."
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience [ETH.MESH.03736120-27]
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience dated in 2003 (8 pgs)
Gynecare Prolift IFU dated 2009 [ETH-10977 – 10983]
Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile [ETH.MESH.04181761-2]
Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique (30 pgs)
Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique [ETH-07252 – ETH-7281]
Gynecare Prosima - Content for Ethicon360.com
Gynecare Prosima (K063562) Summary of Safety and Effectiveness
Gynecare Prosima Pelvic Floor Repair System: An expert interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the inventor of the Gynecare Prosima system [ETH.MESH.06255523-34]
Gynecare Prosima updates to ethicon360.com
Gynecare TVT Obturator System Sales Materials [ETH.MESH.161953-54]
Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician [ETH.MESH.10220659]
Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides [ETH.MESH.08107354]
Gynemesh PS Approval File from FDA website (K013718)
History of TVT [ETH.MESH.03932912-14]
History of TVT-O [ETH.MESH.3932909-11]
Jan 2007 email re delaying launch [ETH.MESH.18844812]
JJM.Mesh.00043703 Response Statement and FAQs – FDA Notification about use of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence
Kanerviko email re 40000 page response to 522 [ETH.MESH.04931596]
KOL Interview [ETH.MESH.4048515-20]
Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT [ETH.MESH.04939001]
Letter from FDA re: Postmarket Surveillance (PS) Study: PS120044 (Proxima 522 Order)
Letter to EWHU Field Sales Force from Price St. Hilaire dated 10.23.06 re: criteria for surgeons being trained for Gynecare Prolift (1 pg)

## Production Materials

Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair [ETH.MESH.00031324 – 31325]
Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer [ETH.MESH.1222075-79]
Letters to and from the FDA re: Prolene, Polypropylene Nonabsorbable Surgical Suture, USP.
Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out [ETH.MESH.262089-123]
Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competitive Devices (BE02004-1641) [ETH.MESH.1809080-81]
Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) RiskAnalysis [ETH.MESH.1784779-82]
Memo re: VOC on new Laser Cut TVT Mesh [ETH.MESH.6878438-39]
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